SUMMARY STATEMENT

(Privileged Communication)

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Release Date: **04/05/2023**
Revised Date:

Application Number: **1 F30 AG084163-01**

GILMER,GABRIELLE
Spaulding Rehabilitation Hospital
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Charlestown, MA 021293109

Review Group:	**ZRG1 F10B-C (20)** **Center for Scientific Review Special Emphasis Panel** **Fellowships: Musculoskeletal, Rehabilitation and Skin Sciences**
Meeting Date:	**03/08/2023**
Council:	**MAY 2023** ***PCC:*** **1BMSKJW**
Requested Start:	**07/01/2023**

Project Title:	**Menopausal Knee-ds: Elucidating mechanisms and treatments for knee osteoarthritis**
	***Requested*: 4 Years**
Sponsor:	**Ambrosio, Fabrisia**
Department:	
Organization:	**SPAULDING REHABILITATION HOSPITAL**
City, State:	**CHARLESTOWN MASSACHUSETTS**
SRG Action:	**Impact Score:10**
Next Steps:	**Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects:	**10-No human subjects involved**
Animal Subjects:	**30-Vertebrate animals involved - no SRG concerns noted**

1F30AG084163-01 Gilmer, Gabrielle

RESUME AND SUMMARY OF DISCUSSION: In this F30 dual degree predoctoral fellowship application, the candidate proposes training in cellular and molecular pathology with an emphasis on regenerative rehabilitation. The study is centered on better understanding the mechanisms that regulate knee osteoarthritis (KOA) in postmenopausal women using a chemically induced post-menopausal mouse model of KOA. Reviewers agreed that the Applicant is outstanding and praised her decision of pursuing a career in the field of therapy development for treating joint injuries in women. Reviewers noted the exceptional grades and the extensive list of academic accomplishments achieved to date, including several honors, multiple awards, numerous fellowships and, remarkably, 25 peer-reviewed publications in high impact factors journals including 10 as a first author. The letters of support depict the Applicant as an exceptional candidate with a keen intellect and accurate scientific intuition, strong leadership skills and willingness to work hard. The Sponsor was described as a leader in the field of skeletal muscle biology; to have the mentoring skills and funds necessary to support the research plan proposed by the candidate; and to be highly committed to the success of the Applicant's career goals. The multidisciplinary mentoring team composed of former trainees in the Sponsor's laboratory as well as members of her thesis committee was thought to bring the additional expertise in KOA, synthetic biology, menopause and aging necessary to guide the Applicant through the proposed research training plan. The environment was defined as outstanding and highly committed to students' training. Additional strength in the proposal included a well-written application, defined by some of the Reviewers as a pleasure to read; a rigorous approach; the well laid-out training goals; and a well-rationalized research training plan with ample opportunities for the Applicant to acquire the skills in molecular biology needed to progress her career as a clinician scientist. Weaknesses noted by the Reviewers were minor to negligible and included the lack of details in the statistical analyses proposed and the lack of a biostatistician in the mentoring team. Following discussion, the panel agreed that the strengths identified in the Applicant, Sponsor, mentoring team, clinical relevance of the study and training plan largely outweighed the few weaknesses noted in the research plan. The overall impact and training potential of the application was assessed as very high.

DESCRIPTION (provided by applicant): Background: As of 2020, an estimated 654.1 million adults live with knee osteoarthritis (KOA), and women who are post-menopausal are nearly twice as likely to develop KOA compared to men. Despite this, most animal studies on KOA include only males, and, of the few studies utilizing females, menopause is typically not included, as it is not a naturally occurring process in non-primates. As such, there is a paucity of literature aimed at understanding mechanisms of menopause associated KOA and a corresponding absence of treatment interventions specifically for post-menopausal people with KOA. As a part of my PhD work thus far, I have developed a chemically-induced menopause model by injecting middle-aged female mice with 4- vinylcyclohexene diepoxide (VCD). I have confirmed this model displays a menopausal phenotype, including perimenopause, and that these mice display more severe KOA than age-matched, non-menopausal mice. The research goals of this fellowship are to interrogate mechanisms of menopause-induced KOA using our VCD model (Specific Aim 1) and employ synthetic biology techniques to lay the groundwork for new treatment modalities for menopause-indued KOA and (Specific Aim 2). Specific Aim 1: A component of E3 ubiquitin ligase was recently identified in a GWAS meta-analysis as a unique contributor to OA in women. As such, I will interrogate the role of estradiol-regulated, ubiquitin proteolysis in mediating menopause-induced KOA using our VCD menopause model. Changes in ubiquitin proteolysis signaling across perimenopause, menopause, and with estradiol treatment will be quantified both in vivo and in

vitro. We hypothesize that (1) menopause induction will disrupt ubiquitin proteolysis activity and (2) estradiol treatment started early in menopause will restore ubiquitin proteolysis signaling and ultimately quinch menopausal KOA. Specific Aim 2: I will design an estradiol-regulated controls circuit to modulate a gene of interest (GOI) in vitro. A significant drop in estradiol is a principal physiological change associated with menopause, and an estradiol- repressed promoter will be designed to turn the circuit on. GOI candidates will be generated from previous studies and will be systematically tested to determine ideality for mediating chondrogenicity. We hypothesize that a genetic controls circuit modulated by estradiol will attenuate chondrocyte health in vitro. Impact: To support my fellowship, I have assembled a multidisciplinary team with expertise in KOA, menopause, aging, and synthetic biology. I have strategized with my mentoring team to design a rigorous training plan that will take advantage of the extraordinary research environments offered at my sponsor's new institution (Spaulding Rehabilitation, Harvard Medical School) and the University of Pittsburgh, where I remain a full-time student. This fellowship will propel me towards my long-term goals of being a physician-scientist who practices orthopedic surgery and research leader in joint diseases and injuries presenting in women.

PUBLIC HEALTH RELEVANCE: Post-menopausal women are twice as likely to develop knee osteoarthritis than men; yet there are currently no animal studies aimed at understanding how natural menopause propagates knee osteoarthritis and, thus, no specific treatments for post-menopausal people with knee osteoarthritis. This proposal interrogates the role of pathologic protein turnover in menopause-induced knee osteoarthritis and employs synthetic biology techniques to develop an estradiol-regulated genetic controls circuit. Completion of these studies will provide insight into the underlying mechanisms of menopause-induced knee osteoarthritis and provide the first steppingstone for gene- therapy treatments for this disease.

CRITIQUE 1

Fellowship Applicant: 1
Sponsors, Collaborators, and Consultants: 1
Research Training Plan: 1
Training Potential: 1
Institutional Environment & Commitment to Training: 1

Overall Impact: This is an F30 application for an MD/PhD candidate proposing to investigate mechanisms of knee osteoarthritis (KOA) in postmenopausal women (who are 2x greater risk than same aged men) using a chemically induced post-menopausal rodent model of KOA. The candidate's career goal is serving as a physician scientist in orthopedic surgery leading research on joint diseases and injuries in women. The candidate has an outstanding productivity record beginning as an undergraduate with a total of 25 manuscripts, 10 as first author. The PI has an excellent to outstanding academic record, has received multiple regional and local awards, and serves on multiple local committees. Undergrad work was focused on in-human biomechanics followed by a post-bac at NIH learning bioengineering and mass spec proteomics skills while studying nephron biology. Graduate work has focused on KOA in rodents and a discrepancy between male>female rodent KOA versus women>men KOA led to PI's development of the chemically induced post- menopausal KOA model. The training plan includes didactics of PhD (completed) and clinical rotations at the PI's primary institution supplemented with additional virtual and in-person seminars and scientific meetings. The

research plan will address underlying mechanisms of KOA in menopause/postmenopausal women. Aim 1 rationale is based on protein turnover and ubiquitin ligase having been implicated in OA and ubiquitin and estradiol signaling overlaps in other tissues. Aim 1 will use existing samples and evaluate the hypothesis that time-dependent, estradiol signaling regulates ubiquitin proteolysis. Specifically, the immunohistochemistry will be used to assess the expression of ubiquitin signaling components over time (control, peri, early menopause, late-menopause) and across knee compartments. Subsequently, for the times above, estradiol or a vehicle control will be administered for determination of effects on ubiquitin signaling and joint compartment pathologies. Also, chondrocytes will be isolated and subjected to live cell imaging of protein ubiquitination and fluorescent based proteasome activity. Aim 2 will evaluate the potential for a synthetic genetic circuit to reprogram implicated genes. 18 genes identified in a GWAS meta-analysis will be combined with estradiol-repressed promoters and transfected into chondrocytes so that as estrogen declines, these genes will turn on and then remain active in the absence of estradiol. Candidate promoters will be identified from a breast cancer database and tested for estradiol responsiveness using a firefly luciferase system. Candidate genes of interest will be compared for those best preserving chondrogenicity defined as imaging flow cytometry measures of Sox9, type II collagen, and aggrecan as well as reversal of gene expression with and without estrogen presence. Experimental design is well-described, rationalized, and based on clear hypotheses. Alternative strategies are outlined for each project component. Findings are likely meaningful regardless of outcomes. Overall, this is an outstanding application.

1. Fellowship Applicant:

Strengths

- Outstanding productivity.
- Focused on unique and impactful scientific niche (orthopedic injuries in women) particularly relevant for an MD/PhD.
- Serves on numerous committees (i.e., Founder American Physician Scientist Local Chapter at Pitt) and has received numerous awards (i.e., first place poster and travel awards, Regenerative Rehabilitation Symposium).
- Undergrad research included in human studies with biomechanical assessments and provided additional skills in coding, statistical analyses, and writing.
- Sponsors statements consistently rank PI in top 1-2% of trainees.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- Sponsor is leader in the field.
- Mentor team adds expertise in knee osteoarthritis, menopause and HRT, and synthetic biology.
- Sponsor statements express clear commitment to training and availability of appropriate resources.

Weaknesses

- None noted.

3. Research Training Plan:

Strengths

- Plan targets PIs goal of focusing on women-specific orthopedic health.
- Rationale is based on PIs recognition of discrepancy between male/female KOA and women/men KOA and subsequent development of a chemically-induced menopausal model of KOA in which female mice have more KOA than controls.
- Model provides a more “natural” menopause than ovarectomized mice.

Weaknesses

- None noted.

4. Training Potential:

Strengths

- Training leverages opportunities at PI’s primary institution (Pitt) as well as sponsor’s new institution (Spaulding/Harvard).
- Proposed research will expand skills in animal procedures, immunohistochemistry/immunofluorescence, and cell culture and provide new skills in microscopic imaging, including live cell imaging, molecular biology (promoter design and generation, cellular transfection, and stable genetic engineering).
- Persons experienced in these skills are in close proximity.
- Will add to MD training additional clinical training during fellowship/PhD work with monthly OR time.
- Weekly virtual and biweekly in-person seminars are proposed as well as attendance and presentations at multiple scientific conferences.
- Nice addition of mental health care plan.

Weaknesses

- Unclear what “working with….on telemedicine” entails or skills this provides. (Minor)

5. Institutional Environment & Commitment to Training:

Strengths

- Outstanding especially when leveraging those at two outstanding institutions.

Weaknesses

- None noted.

Protections for Human Subjects

Not Applicable (No Human Subjects)

Vertebrate Animals

YES, all criteria addressed

Biohazards

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research

Acceptable

Comments on Format (Required):

- Rigorous prior and ongoing training is outlined in multiple application components.

Comments on Subject Matter (Required):

- See above.

Comments on Faculty Participation (Required):

- See above.

Comments on Duration (Required):

- See above.

Comments on Frequency (Required):

- See above.

Applications from Foreign Organizations

Not Applicable

Select Agents

Not Applicable (No Select Agents)

Resource Sharing Plans

Acceptable

Authentication of Key Biological and/or Chemical Resources

Acceptable

Budget and Period of Support

Recommend as Requested

CRITIQUE 2

Fellowship Applicant: 1
Sponsors, Collaborators, and Consultants: 1
Research Training Plan: 2
Training Potential: 1
Institutional Environment & Commitment to Training: 1

Overall Impact: This is a predoctoral F30 application from Gabrielle Gilmer who is an MD/PhD student at the University of Pittsburg being trained at Harvard Medical School. The applicant is expected to get her PhD in Cellular and Molecular Pathology on 05/2025, and her MD degree on 05/2027. The applicant's long-term career goal is to build a comprehensive research and clinical care center that focuses on joint injuries in women. The applicant's long-term research goals are to understand sex differences in joint function and injury, design clinical treatments for joint injuries in women, and to empower women to get back to their movement patterns. The applicant has excellent grades in her PhD and MD coursework, and has an impressive publication record with a total of 25 peer reviewed publications, 10 as first author and 4 from her graduate work (one as first author; 2 more publications are under review). To pursue her research goals, the applicant wants to improve her training in biomechanics and rehabilitation, physiology and informed tissue engineering, and clinical interventions. For this purpose, she is proposing a project to elucidate estradiol-driven mechanisms and treatments for menopause-induced knee osteoarthritis. The sponsor will certainly help the applicant to accomplish her training and career goals as she has history of training at different academic/professional levels, and substantial expertise in regenerative rehabilitation, which combines tissue engineering and physical therapy approaches. The scientific and research environment are optimal, and the letters of reference confirm her accomplishments and research abilities. In summary, this is a very strong applicant with a strong proposal and for that there is a high level of enthusiasm.

1. Fellowship Applicant:

Strengths

- The applicant has a strong academic background with excellent grades in her PhD and MD coursework. (Major strength)
- The applicant's research productivity is reflected in her outstanding publication record (25 peer-reviewed publications: 10 as first author). (Major strength)
- The significance, quality and impact of the applicant's research has been recognized with awards at major research conferences. (Major strength)
- The applicant demonstrates a clear passion and commitment to a research career. (Major strength)
- The letters of reference are quite strong describing the applicant as "ONE of a kind". (Major strength)

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The sponsor, Dr. Ambrosio, (Associate Professor), is an expert in skeletal muscle physiology and function, cellular and tissue engineering therapeutics to improve skeletal muscle healing after injury and disease, regenerative rehabilitation, mechanisms for pathogenic skeletal muscle dysfunction, and biomechanics and assistive technology. (Major strength)
- Dr. Ambrosio has a strong history of mentoring at different professional levels. (Major strength)
- Dr. Ambrosio has NIH funding and other funding sources to support the research training of the applicant. (Major strength)
- There is a strong mentoring team in place including clinical faculty such as Dr. Tanaka who is the Director of the Women's Sports Medicine Program and a practicing orthopedic surgeon at MGH; Dr. Fowler who is a successful orthopedic surgeon-scientist at the University of Pittsburgh; and Dr. Sowa who is an expert in telemedicine at the University of Pittsburgh. (Major strength)

Weaknesses

- None noted.

3. Research Training Plan:

Strengths

- The research plan is significant as it will improve our understanding of estradiol-driven proteolysis as a mechanism of KOA, and will provide valuable information towards alternative treatment options for menopause-induced KOA. (Major strength)
- The proposed research plan is innovative as it will use a novel chemically-induced menopause model that displays more severe KOA than age-matched controls. (Major strength)
- The proposed research plan will provide the additional training that is sought by the applicant. (Major strength)
- The applicant provides strong preliminary data supporting the pursue of her hypotheses. (Major strength)
- The applicant is going to assess KOA as a pathology affecting the whole knee joint: cartilage, synovium, and subchondral bone. (Major strength)
- The applicant has a clear idea of the expected outcomes, considers potential pitfalls and provides alternative strategies. (Major strength)

Weaknesses

- None noted.

4. Training Potential:

Strengths

- The applicant will develop skills that will make her competitive, such as developing novel engineering techniques to design and create menopause-induced genetic control circuits. (Major strength)
- Internal programs such as the "Innovation Hero" will further stimulate the applicant's creativity and boldness in generating new ideas. (Major strength)

Weaknesses

- None noted.

5. Institutional Environment & Commitment to Training:

Strengths

- Harvard Medical School and the University of Pittsburg provide excellent scientific and research environments for the successful training of the applicant. (Major strength)
- The applicant will have access to the required equipment to perform the proposed research plan. (Major strength)

Weaknesses

- None noted.

Protections for Human Subjects

Not Applicable (No Human Subjects)

Vertebrate Animals

YES, all criteria addressed

- Comprehensive Vertebrate Animals section including description of vertebrate animal procedures, justifications for species selection, procedures to minimize pain and distress, and methods of euthanasia.

Biohazards

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research

Acceptable

Comments on Format (Required):

- In person and group discussions.

Comments on Subject Matter (Required):

- Ethics.
- Ethics, Law, and Professionalism: informed consent, genetic manipulation, and confidentiality.
- Courses in HIPPA, informed consent, and bloodbome pathogens.
- CITI courses on RCR, Biomedical Human Subjects Research, Conflicts of Interest, Information Privacy & Security, Working with Mice in Research Settings, Working with Genetically Modified Mice in Research Settings, Working with Small Animals, Animal Care and Use - Working with the IACUC, Reducing Pain and Distress in Laboratory Mice and Rats, Aseptic Surgery, and Rodent Anesthesia.

- Lectures on IRB protocol development, methods to enhance reproducibility and transparency in reporting and preprints.

Comments on Faculty Participation (Required):

- Faculty from different departments.

Comments on Duration (Required):

- Ethics course consisted of four 2-hour sessions.
- Ethics, Law, and Professionalism was 2-hour sessions per week for 15 weeks.

Comments on Frequency (Required):

- The applicant will continue to maintain her RCR up to data including her CITI trainings.

Applications from Foreign Organizations

Not Applicable

Select Agents

Not Applicable (No Select Agents)

Resource Sharing Plans

Acceptable

- Data and resources generated from this application will be shared by the applicant and collaborators through established means.

Authentication of Key Biological and/or Chemical Resources

Acceptable

Budget and Period of Support

Recommend as Requested

CRITIQUE 3

Fellowship Applicant: 1
Sponsors, Collaborators, and Consultants: 2
Research Training Plan: 2
Training Potential: 1
Institutional Environment & Commitment to Training: 1

Overall Impact: This F30 proposal was submitted by a 3rd year MD/PhD candidate with a strong/suitable educational background, a clear career trajectory to eventually serve as a physician-scientist, and impressive documented academic achievements. The applicant has achieved 25

published manuscripts, 10 as first author. The primary sponsor is a noted expert in tissue physiology and regenerative medicine/rehabilitation, directing a training center on this topic, and is highly suitable as a mentor. While not listed as co-sponsors, there is an extensive mentoring team that will address other important aspects of the proposed project, including synthetic biology techniques, and deliver comprehensive academic training. The applicant will benefit from resources and collaboration spanning two highly ranked institutions (University of Pittsburgh and Harvard). The proposed project aims to study the biological mechanisms underlying menopause-induced knee osteoarthritis using an animal model and assess synthetic techniques as a possible treatment modality. This project has important implications to studying this disease as previous animal models have relied on male specimens although menopause-induced knee osteoarthritis is common and specific to female sex. The aims are well structured to first perform an in-vitro/vivo assessment on the relationship between menopause induction and proteolysis activity and the role of estradiol treatment, followed by exploration of effects of an estradiol-regulated controls circuit on chondrocyte health. The environment and training potential are exceptional, and the research plan is well structured and logical with testable hypotheses. There are some minor concerns regarding the statistical plan, but these are easily addressed.

1. Fellowship Applicant:

Strengths

- The applicant is an MD/PhD candidate with an exceptionally strong educational background that is highly suitable for pursuing the proposed research training plan.
- The applicant has an impressive history of academic achievements (25 publications, 10 first author), is recipient of a T32 training award, has extended relevant post-bac training, and a clear appreciation of the research process and role of a physician-scientist, which is the stated career goal.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The primary sponsor, Dr. Ambrosio, is a leading expert in tissue physiology and regenerative medicine/rehabilitation and has a strong record of research funding and mentorship experience. She is also director of the NIH-funded Alliance for Regenerative Rehabilitation Research and Training program.
- Mentor team will provide additional relevant training in various aspects of research and professional development.

Weaknesses

- A named biostatistician co-sponsor would strengthen the proposal and training. (Moderate)
- There is an extensive list of co-mentors, although none are explicitly listed as co-sponsors. The mentorship of Dr. Silver seems highly critical to the candidate’s training and perhaps warrants elevation to this status, alongside inclusion of the appropriate documents to review their background and qualifications (biosketch). (Minor)

3. Research Training Plan:

Strengths

- The proposed research training plan timeline is detailed and feasible, engendering confidence in successfully carrying out the proposed activities. (Major)
- The proposed project is impactful as it aims to study the biological mechanisms underlying menopause-induced knee osteoarthritis through a specific animal model and assess synthetic control techniques as a possible treatment modality. There are well structured aims describing in-vitro and in-vivo work with testable hypotheses. (Major)
- Preliminary work is relevant and rigorous to support the proposed aims. (Major)
- The power analysis appear appropriate for Aims 1 and 2. (Major)
- Potential problems and solutions have been sufficiently detailed. (Moderate)

Weaknesses

- While implied, it is not explicitly stated that the Aims1a-b statistical analysis will be a two-way repeated measured ANOVA assessing the main effect of group and time. (Minor)
- A description of non-parametric analyses in the case of non-normal data is described, but the procedure to assess normality is not detailed. (Minor)

4. Training Potential:

Strengths

- The training plan is detailed and will provide valuable experience to develop both academically and professionally. (Major)
- There is ample opportunity for the applicant to benefit from collaboration and external mentorship across both institutions (U Pitt and Harvard) to help support the desired trajectory to become a productive physician-scientist. (Major)
- The applicant will continue to receive research and clinical training through the dual-training program, which will be a valuable asset to developing her research skillset. (Major)

Weaknesses

- Formal training in grantsmanship would help strengthen the training plan. (Minor)

5. Institutional Environment & Commitment to Training:

Strengths

- The University of Pittsburgh Medical Scientist Training Program is a highly ranked and well-structed MD/PhD dual-training program and provides an excellent environment for research training given the available resources and highly productive research faculty. (Major)
- the institution and mentors appear highly committed to training and will surely support the applicant’s trajectory of becoming an independent physician-scientist. (Major)

Weaknesses

- None noted.

Protections for Human Subjects

Not Applicable (No Human Subjects)

Vertebrate Animals

YES, all criteria addressed

- Adequately described in the animal studies procedures.

Biohazards

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research

Acceptable

Comments on Format (Required):

- Acceptable.

Comments on Subject Matter (Required):

- Acceptable.

Comments on Faculty Participation (Required):

- Acceptable.

Comments on Duration (Required):

- Acceptable.

Comments on Frequency (Required):

- Acceptable.

Applications from Foreign Organizations

Not Applicable

Select Agents

Not Applicable (No Select Agents)

Resource Sharing Plans

Acceptable

Authentication of Key Biological and/or Chemical Resources

Acceptable

- Adequately described.

Budget and Period of Support

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

VERTEBRATE ANIMALS: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 F30 AG084163-01; PI Name: Gilmer, Gabrielle

NIH has modified its policy regarding the receipt of resubmissions (amended applications).See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Center for Scientific Review Special Emphasis Panel
CENTER FOR SCIENTIFIC REVIEW
Fellowships: Musculoskeletal, Rehabilitation and Skin Sciences
ZRG1 F10B-C (20)
03/08/2023 - 03/09/2023

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-22-044 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-044.html, including removal of the application from immediate review.

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